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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,761	06/18/2001	Rolando Barbucci	1756	2132

7590

03/10/2003

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EXAMINER

WHITE, EVERETT NMN

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 03/10/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/830,761

Applicant(s)

BARBUCCI ET AL.

Examiner

EVERETT WHITE

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12, 14, 15 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12, 14, 15 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

1. The amendment filed December 27, 2002 has been received, entered and carefully considered. The amendment affects the instant application accordingly:
 - (A) Claims 1-4, 13 and 16 have been canceled.
 - (B) New Claim 17 has been added.
 - (D) Claims 12, 14 and 15 have been amended.
 - (E) Comments regarding Office Action have been provided drawn to
 - (a) 112, 2nd paragraph rejection, which has been withdrawn;
 - (b) Objection of claims, which has been withdrawn;
 - (c) 102(b) rejection, which has been maintained for the reasons of record;
 - (d) 102(e) rejection, which has been maintained for the reasons of record; &
 - (e) 103(a) rejection, which has been maintained for the reasons of record.
2. Claims 12, 14, 15 and 17 are pending in the case.
3. The text of those sections of title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

1. Claims 15 and 17 stand rejected under 35 U.S.C. 102(b) as being anticipated by Pouyani et al (US Patent No. 5,616,568) for the reasons already of record on pages 3 and 4 of the Office Action mailed October 2, 2002.

Applicant's arguments filed December 27, 2002 have been fully considered but they are not persuasive. Applicants argue against the rejection of Claim 17 on the grounds that original Claim 4 has been included in Claim 17. Applicants argue that if the rejection was not applied originally to Claim 4, then the rejection now should not be applicable to Claim 17. This argument is not persuasive since original Claim 4 was improper under the 2nd paragraph of 35 U.S.C. 112. The subject matter of Claim 4 has been amended and is now included in Claim 17. It is also noted that the subject matter in original Claim 4 was contained in original Claim 3, which was properly rejected as being anticipated by the Pouyani et al patent. Claim 17 now contains all the information that was set forth in original Claim 3.

Applicants further argue that the –NH–NH–moiety, which is disclosed as part of the hydrazide compound in the Pouyani et al patent is not included in the diamine compound of the instant claims. This argument is not persuasive since Claim 17 broadly defines “A” as a linear C₂–C₆ alkylene chain that may be substituted by amino groups, which may include a –NH–NH–moiety when the formula R₁NH–A–HNR₂ is considered along with “A” being substituted by an amino group. In order to overcome this rejection, further clarification in Claim 17 of how the amino group is substituted onto the “A” group is required.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a hyaluronic acid molecule which is cross-linked with another hyaluronic acid molecule) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Accordingly, the rejection of Claims 15 and 17 under 35 U.S.C. 102(b) as being anticipated by the Pouyani et al patent is maintained for the reasons of record.

2. Claims 14, 15 and 17 stand rejected under 35 U.S.C. 102(e) as being anticipated by Prestwich et al (US Patent No. 5,874,417) for the reasons already of record on page 4 of the Office Action mailed October 2, 2002.

Applicant's arguments filed December 27, 2002 have been fully considered but they are not persuasive. Applicants argue against the rejection of Claim 17 on the grounds that original Claim 4 has been included in Claim 17. Applicants argue that if the rejection was not applied originally to Claim 4, then the rejection now should not be applicable to Claim 17. This argument is not persuasive since original Claim 4 was improper under the 2nd paragraph of 35 U.S.C. 112. The subject matter of Claim 4 has been amended and is now included in Claim 17. It is also noted that the subject matter in original Claim 4 was contained in original Claim 3, which was properly rejected as being anticipated by the Prestwich et al patent. Claim 17 now contains all the information that was set forth in original Claim 3.

Applicants further argue that the –NH-NH-moiety, which is disclosed as part of the hydrazide compound in the Prestwich et al patent is not included in the diamine compound of the instant claims. This argument is not persuasive since Claim 17 broadly defines “A” as a linear C₂-C₆ alkylene chain that may be substituted by amino groups, which may include a –NH-NH-moiety when the formula R₁NH-A-HNR₂ is considered along with “A” being substituted by an amino group. In order to overcome this rejection, further clarification in Claim 17 of how the amino group is substituted onto the “A” group is required.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a hyaluronic acid molecule which is cross-linked with another hyaluronic acid molecule) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Accordingly, the rejection of Claims 14, 15 and 17 under 35 U.S.C. 102(e) as being anticipated by the Prestwich et al patent is maintained for the reasons of record.

Claim Rejections - 35 USC § 103

3. Claims 12, 14, 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prestwich et al (US Patent No. 5,874,417) in view of Galin et al (US Patent No. 5,944,753) for the reasons already of record on pages 5-7 of the Office Action mailed October 2, 2002.

Applicant's arguments filed December 27, 2002 have been fully considered but they are not persuasive. Applicants argue against the rejection of Claim 17 on the grounds that original Claim 4 has been included in Claim 17. Applicants argue that if the rejection was not applied originally to Claim 4, then the rejection now should not be applicable to Claim 17. This argument is not persuasive since original Claim 4 was improper under the 2nd paragraph of 35 U.S.C. 112. The subject matter of Claim 4 has been amended and is now included in Claim 17. It is also noted that the subject matter in original Claim 4 was contained in original Claim 3, which was properly rejected as

being unpatentable over the Prestwich et al patent in view of the Galin et al patent .
Claim 17 now contains all the information that was set forth in original Claim 3.

Applicants further argue that the –NH–NH–moiety, which is disclosed as part of the hydrazide compound in the Prestwich et al patent is not included in the diamine compound of the instant claims. This argument is not persuasive since Claim 17 broadly defines “A” as a linear C₂–C₆ alkylene chain that may be substituted by amino groups, which may include a –NH–NH–moiety when the formula R₁NH–A–HNR₂ is considered along with “A” being substituted by an amino group. In order to overcome this rejection, further clarification in Claim 17 of how the amino group is substituted onto the “A” group is required.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a hyaluronic acid molecule may be cross-linked with another hyaluronic acid molecule) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, a person of ordinary skill in this art would combine the teachings of the Prestwich et al patent with the teachings of the Galin et al patent since both patents disclose the attachment of other compound groups to hyaluronic acid.

Accordingly, the rejection of Claims 12, 14, 15 and 17 under 35 U.S.C. 103(a) as being unpatentable over the Prestwich et al patent in view of the Galin et al patent is maintained for the reasons of record.

Summary

4. All the pending claims are rejected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Examiner's Telephone Number, Fax Number, and Other Information

5. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E. White

E. White



James O. Wilson
Supervisory Primary Examiner
Technology Center 1600